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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 407,605	09 28 1999	ALLAN M. MILLER	10278 009001	2966

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12 31 2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/407,605

Applicant(s)

MILLER ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on 10/3/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-79, 81-94, 96-108, 110-120, 122-125, 127-130 and 132-135 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 64-79, 81-94, 96-108, 110-120, 122-125, 127-130 and 132-135 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 17) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other _____

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DETAILED ACTION

1. Applicant's response to the Office Action mailed March 29, 2001 in Paper No. 11 on October 3, 2001 is acknowledged. It is noted that applicant filed a substitute declaration on October 3, 2001 in Paper No. 12.
2. Claims 80, 95, 109, 121, 126 and 131 have been canceled. Claims 64, 66, 67, 69, 72, 73, 75, 76, 78, 79, 81-83, 85-87, 89-92, 94, 97-106, 108, 113-116, 119, 120, 125, 130 and 135 have been amended. Claims 64-79, 81-94, 96-108, 110-120, 122-125, 127-130, 132-135 are pending.
3. The following grounds of rejection are or remain applicable :

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of

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Claims 64-79, 81-94, 96-108, 110-120, 122-125, 127-130, 132-135 are rejected under 35

U.S.C. 112, first paragraph, because the specification while being enabling for a synthetic nucleic acid encoding a protein, does not reasonably provide enablement for the any fragment thereof or portion thereof. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to:

I. Quantity of Experimentation Necessary:

The claimed invention is directed to a synthetic nucleic acid sequence which encodes a protein or a fragment of the claimed protein. The claims do not recite any functional limitation or specific sequence for the claimed nucleic acid or protein. Further, the specification does not adequately describe or exemplify "fragments thereof" in association with the claimed invention. Therefore, as the specification lacks guidance as to special features of the claimed fragment such as size, function and no direction is provided as to the claimed portion thereof one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims. To examine every fragment to determine which one had activity would require undue experimentation.

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The specification does not disclose one reasonable method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim.

III. Presence or absence of working examples:

The working examples provided do not demonstrate the claimed fragments in association with the claimed invention.

IV. Nature of the Invention:

The nature of the invention is a synthetic nucleic acid sequence that encodes a protein or fragment thereof or portion thereof. However, the specification does not provide sufficient guidance/direction to enable the full scope of the claimed invention as the claimed fragment is not described by size, length or biological activity.

V. State of the prior art and Relative skill of those in the art:

As the prior art is silent on the claimed sequences a high level of skill was required at the time the application was filed.

VI. Predictability or unpredictability of the art:

Since very little is known in the prior art about the nature of the invention renders the art

invention is order to be enabling

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VII. Breadth of the claims:

The breadth of the claims are very broad and encompass an unspecified amount of fragments which are not adequately described or demonstrated in the specification.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 64-79, 81-94, 96-108, 110-120, 122-125, 127-130, 132-135 are pending are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 and the dependent claims hereto remain indefinite because the claims do not recite a specific sequence in reciting for example "150 codons" (see also claims 69, 73, 81, 85, 89,

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5. Applicant's response filed October 3, 2001 has been fully considered. Note that the rejections under 35 U.S.C. 112, first and second paragraph remains. Regarding the rejection under 35 U.S.C. 112, first paragraph, this ground of rejection was necessitated by the amendments to the claims. With regard to the rejection under 35 U.S.C. 112, second paragraph, the rejection over all claims remain because the claims do not recite a specific sequence yet refer to certain numbers of codons or amino acid residues. The response at page 15 argues that the claims have been amended to clarify that the stretch of replaced codons correlates to the sequence of the recited protein. However, this argument is not convincing as the claims do not recite a specific sequence for the claimed protein either. Applicant need to provide the sequence identifiers in the claims that corresponds to the recited amino acid residues or codons. Thus, the rejection has been maintained.

Conclusion

6. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

months from the mailing date of this final action, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, Ph.D., can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096

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Hope Robinson, MS *HR*

Patent Examiner

Christopher S. F. Low
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